RegulatoryInformation/Legislation/FederalFoodDrugandCosmeticAct FDCAct/FDCActChapterVDrugs andDevices/default.htm) provides that an HDE holder immediately notify the Agency if the number of devices distributed during any calendar year exceeds the ADN. Section 520(m)(6)(C) of the FD&C Act provides that an HDE holder may petition to modify the ADN if additional information arises.

On August 5, 2008, FDA issued a guidance entitled ''Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and Food and Drug Administration Staff—Humanitarian Device Exemption (HDE) Regulation: Questions and Answers'' (*http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110203.pdf*). The guidance was developed and issued prior to the enactment of FDASIA, and certain sections of this guidance may no longer be current as a result of FDASIA. The Center for Devices and Radiological Health and the Center for Biologics Evaluation and Research are currently working on a draft HDE guidance, that when finalized, will represent the FDA's current thinking on this topic.

FDA is requesting OMB approval for the collection of information required under the statutory mandate of sections 515A (21 U.S.C. 360e-1) and 520(m) of the FD&C Act as amended.

In the **Federal Register** of December 17, 2012 (77 FR 74667), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity/section of FD&C Act (as amended) or FDASIA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Pediatric Subpopulation and Patient Information—515A(a)(2) of the FD&C Act	6	1	6	100	600
Exemption from Profit Prohibition Information—520(m)(6)(A)(i) and (ii) of the FD&C Act	3	1	3	50	150
Request for Determination of Eligibility Criteria—613(b) of FDASIA	2	1	2	10	20
ADN Notification—520(m)(6)(A)(iii) of the FD&C Act	1	1	1	100	100
ADN Modification—520(m)(6)(C) of the FD&C Act	5	1	5	100	500
Total					1,370

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

FDA based these estimates on the number of original HDE applications received in the period between October 1, 2008, and September 30, 2011. During that time, FDA's Center for Devices and Radiological Health received 19 original HDE applications, or about 6 per year. FDA estimates that for each year we will receive six HDE applications and that three of these applications will be indicated for pediatric use. The request for determination of eligibility criteria is new under section 613(b) of FDASIA. We estimate that we will receive approximately two such requests per year. Historically, no companies have exceeded the ADN; and under FDASIA the ADN has expanded to a minimum of 4,000. Therefore, FDA estimates that very few or no HDE holders will notify the Agency that the number of devices distributed in the year has exceeded the ADN. FDA estimates that five HDE holders will petition to have the ADN modified due to additional information on the number of individuals affected by the disease or condition.

The draft guidance refers also to previously approved collections of information found in FDA regulations. The collections of information in 21 CFR part 803 have been approved under OMB control number 0910–0437; the collections of information in 21 CFR part 812 have been approved under OMB control number 0910–0078; the collections of information in 21 CFR part 807, subpart E, have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 814, subparts A, B, and C, have been approved under OMB control number 0910–0231; the collection of information in 21 CFR parts 50 and 56 have been approved under OMB control number 0910–0130; the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073; the collections of information in 21 CFR part 814, subpart H, have been approved under OMB control number 0910–0332; and the collection of information requirements in 21 CFR 10.30 have been approved under OMB control number 0910–0183.

Dated: March 29, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07696 Filed 4–2–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0362]

Draft Guidance for Industry and Food and Drug Administration Staff; Glass Syringes for Delivering Drug and Biological Products: Technical Information To Supplement International Organization for Standardization Standard 11040–4; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of draft guidance for industry and FDA staff entitled ''Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040–4.'' These supplemental data are necessary for FDA to ensure the safe and effective use of glass syringes that comply with the ISO 11040–4 standard when connected to devices (''connecting devices'') that comply with the ISO 594–2 standard.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by July 2, 2013.

ADDRESSES: Submit written requests for single printed copies of the draft guidance to the Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129; Silver Spring, MD 20993. Send one self-addressed adhesive label to assist the office in processing your requests. The guidance may also be obtained by mail by calling the Office of Combination Products at 301–796–8930. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Patricia Y. Love, Office of Combination Products, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, rm. 5129, Silver Spring, MD 20993.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry entitled ''Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040–4.'' This document provides guidance to sponsors seeking to rely on conformity to ISO Standard 11040–4 in submissions for glass syringes products. FDA has become aware of adverse events and product quality events related to connectivity problems when certain glass syringes are used with connecting devices, including connecting devices to conform to the FDA-recognized ISO 594–2 standard. Accordingly, FDA has determined that, for glass syringes, demonstrating conformity to the ISO 11040–4 standard alone does not ensure that the glass syringe can be properly connected to connecting devices. Therefore, this guidance document identifies additional, technical information that should be included in an investigational device exemption (IDE), humanitarian device exemption (HDE), 510(k), or postmarket application (PMA) for a glass syringe product, or in an investigational new drug application (IND), a biologics license application (BLA), new drug application (NDA), or abbreviated new drug application (ANDA) for a drug or biological product that is delivered with such a glass syringe product, to demonstrate that the glass syringe can be properly connected to connecting devices.

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on ''Glass Syringes for Delivering Drug and Biological Products: Technical Information to Supplement International Organization for Standardization (ISO) Standard 11040–4.'' It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statutes and regulations.

II. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Electronic Access

Persons with access to the Internet may obtain the document at either *http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm* or *http://www.regulations.gov.*

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in 21 CFR part 314 for NDAs have been approved under OMB control number 0910–0001. The collections of information in 21 CFR part 601 for BLAs have been approved under OMB control number 0910–0338. The collections of information in 21 CFR part 814 subpart B for PMAs have been approved under OMB control number 0910–0231. The collections of information in FD&C Act subpart E for 510(k) notifications have been approved under OMB control number 0901–0120.

Dated: March 28, 2013.

Peter Lurie,

Acting Associate Commissioner for Policy and Planning.

[FR Doc. 2013–07685 Filed 4–2–13; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Comment Request

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects (Section 3506(c)(2)(A) of Title 44, United States Code, as amended by the Paperwork Reduction Act of 1995, Pub. L. 104–13), the Health Resources and Services Administration (HRSA) publishes periodic summaries of proposed projects being developed for submission to the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995. To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Reports Clearance Officer at (301) 443–1984.

HRSA especially requests comments on: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions, (2) the accuracy of the estimated burden, (3) ways to enhance the quality, utility, and clarity of the information to be collected, and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Information Collection Request Title: Primary Care Faculty Development Initiative (OMB No. 0915-xxxx)—[New].

Abstract: HRSA's Bureau of Health Professions, Division of Medicine and Dentistry, has contracted with Oregon Health and Science University (OHSU), contract HHSH250201200023C, to conduct the planning, execution, and evaluation of a nationally based, longitudinal Primary Care Faculty Development Initiative (PCFDI) demonstration project. OHSU has developed web-based survey